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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

NOVARTIS PHARMACEUTICALS CORPORATION,
NOVARTIS CORPORATION, and NOVARTIS AG,

Plaintiffs,

v.

WOCKHARDT USA LLC and WOCKHARDT
LIMITED

and

SUN PHARMA GLOBAL FZE and
SUN PHARMACEUTICAL INDUSTRIES LIMITED,

Defendants.

Civil Action No.

2:12-cv-03967-SDW-MCA

[Consolidated with Civil Action Nos.
2:12-cv-04393 and 2:13-cv-01028 and
2:13-cv-02379]

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff,

v.

ACTAVIS LLC; APOTEX, INC.; APOTEX, CORP.;
GLAND PHARMA LTD.; DR. REDDY'S
LABORATORIES, INC.; DR. REDDY'S
LABORATORIES LTD.; EMCURE
PHARMACEUTICALS USA, INC.; EMCURE
PHARMACEUTICALS, LTD; HOSPIRA, INC.;
PHARMACEUTICS INTERNATIONAL INC.;
SAGENT PHARMACEUTICALS, IN.; ACS DOBFAR
INFO S.A.; STRIDES, INC.; AGILA SPECIALTIES
PRIVATE LTD.; SUN PHARMA GLOBAL FZE;
CARACO PHARMACEUTICAL LABORATORIES,
LTD.; SUN PHARMACEUTICAL INDUSTRIES LTD.;
WOCKHARDT USA LLC; and WOCKHARDT LTD.,

and

ACCORD HEALTHCARE INC.; FRESENIUS KABI
USA, LLC; and HIKMA FARMACEUTICA S.A.,

Defendants.

NOVARTIS'S ANSWER TO THE COUNTERCLAIMS OF GLAND PHARMA LTD.

Novartis Pharmaceuticals Corporation (“Novartis”), by and through its undersigned attorneys, pursuant to Fed. R. Civ. P. 12, hereby submits this Answer to the counterclaims of Gland Pharma Ltd. (“Gland”) to the Corrected Amended Complaint (D.I. 241, hereinafter “Counterclaims”). For the convenience of the Court, Novartis uses the section headings as posed by Gland in the Counterclaims, and does not purport to concur with the conclusions made therein. Accordingly, this Answer responds to those allegations as follows:

COUNTERCLAIMS

1. Gland repeats and re-alleges each of the foregoing paragraphs of Gland’s Answer and Affirmative Defenses to the Amended Complaint as if fully set forth herein.

Paragraph 1 of the Counterclaims does not contain allegations to which a response is required. To the extent a response is required, Novartis denies the allegations of Paragraph 1.

PARTIES

2. Gland is a corporation organized and existing under the laws of India.

Admitted on information and belief.

3. On information and belief, Novartis is a corporation organized under Delaware law, with its principal place of business in East Hanover, New Jersey.

Admitted.

JURISDICTION AND VENUE

4. These counterclaims arise under the Patent Act of 1952, 35 U.S.C. §§ 1 et seq., and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, et seq. This Court has subject matter jurisdiction to hear this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202

based on an actual controversy between Gland and Novartis created by the claims asserted in the Corrected Amended Complaint filed by Novartis.

Paragraph 4 of the Counterclaims states legal conclusions as to which no response is required. To the extent a response is required, Novartis admits that the Counterclaims purport to arise under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.* and the Declaratory Judgment Act, 28 U.S. C. §§ 2201 *et seq.* Moreover, Novartis does not dispute that this Court has jurisdiction over the subject matter of this action.

5. Venue is proper in this judicial district at least under 28 U.S.C. §§ 1391 and 1400(b), and because Novartis is subject to general personal jurisdiction in this judicial district and has consented to venue by commencing this civil action in this judicial district.

Paragraph 5 of the Counterclaims states a legal conclusion as to which no response is required. To the extent a response is required, for purposes of this action only, Novartis does not dispute that venue is proper in this judicial district.

BACKGROUND

6. U.S. Patent No. 8,324,189 (“the ’189 patent”) issued on December 4, 2012 to Novartis as assignee. Upon information and belief, and based on Novartis’ allegations, Novartis is the current owner of the ’189 patent.

Admitted.

7. On March 21, 2013, Novartis filed its *Corrected Amended Complaint* naming Gland a defendant and alleging infringement of the ’189 patents with respect to Gland’s ANDA No. 202390.

Novartis admits that its Corrected Amended Complaint names Gland as a defendant and alleges infringement of the ’189 patent with respect to ANDA No. 202930 that Gland submitted

in concert with Apotex. Novartis denies the remaining allegations of Paragraph 7.

8. Based on Novartis' allegations in its *Corrected Amended Complaint*, there is now an actual and justiciable controversy between Gland and Novartis regarding, inter alia, the validity and infringement of the '189 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

Paragraph 8 of the Counterclaims states a legal conclusion as to which no response is required. To the extent a response is required, Novartis admits that there exists a justiciable controversy between Novartis and Gland regarding the validity and infringement of the '189 patent.

COUNT I: NON-INFRINGEMENT OF THE '189 PATENT

9. Gland repeats and re-alleges each of the foregoing paragraphs of Gland's

Answer, Defenses, and Counterclaims

Novartis incorporates by reference each of its answers to Paragraphs 1-8 above as if fully set forth herein.

10. The manufacture, use, offer for sale and/or importation into the United States of the products covered by Gland's ANDA No.202390 would not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '189 patent, either literally or under the doctrine of equivalents.

Denied.

COUNT II: INVALIDITY OF THE '189 PATENT

11. Gland repeats and re-alleges each of the foregoing paragraphs of Gland's

Answer, Affirmative Defenses, and Counterclaims

Novartis incorporates by reference each of its answers to Paragraphs 1-10 above as if

fully set forth herein.

12. The claims of the '189 patent are invalid for failing to meet one or more of the requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103 and/or 112, on grounds including those stated in Gland's notice letter to plaintiffs.

Denied.

13. As a further specific example of the grounds of invalidity, and without waiving the right to assert additional grounds of invalidity, the subject matter of the '189 patent would have been obvious to a person of ordinary skill in the art at the time of its alleged invention in light of the scope and content of the prior art (including the prior art disclosure that rapid administration of zoledronic acid could produce renal problems which could be overcome by controlling the rate of administration), the level of ordinary skill in the art, and the differences between the prior art and the subject matter sought to be patented (including specific parameters of the method readily determinable as matters of routine experimentation in conducting ordinary clinical trials required for approval of any new drug).

Denied.

14. Inasmuch as the claims of the '189 patent are invalid, Gland is entitled to a declaration that the claims of said patent are invalid, and that Novartis has no claim for damages or other relief from or against Gland for any alleged infringement thereof.

Denied.

REQUEST FOR RELIEF

Novartis denies that Gland is entitled to the relief it seeks in Paragraphs (A) – (H),

or any other relief with respect to allegations made in the Counterclaims.

JURY DEMAND

Gland's Jury Demand does not contain allegations to which a response is required.

DATED: June 10, 2013

s/ William J. O'Shaughnessy
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that true copies of the foregoing **NOVARTIS'S ANSWER TO THE COUNTERCLAIMS OF GLAND PHARMA LTD.** was caused to be served June 10, 2013, 2013 via email and/or ECF system upon all counsel of record.

By: /s/ William J. O'Shaughnessy
William J. O'Shaughnessy